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10/813,507	03/30/2004	John S. Lollar	13097/3	5299

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,507	LOLLAR, JOHN S.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/22/04, 11/22/05, 7,21,06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence search alingment*.

DETAILED ACTION

This Office Action is a response to Applicant's Election filed October 13, 2006.

Claims 1-26 are pending in the instant application.

Election/Restrictions

Applicant's election, with traverse, of Group VI, Claims 5-18, drawn to an isolated nucleic acid molecule comprising a nucleotide sequence having at least 85% sequence identity to SEQ ID NO:18, vectors, and cells comprising said nucleic acid molecule, and a method of making a polypeptide following expression of said isolated nucleic acid molecule in the reply filed on October 13, 2006 is acknowledged. The traversal is on the ground(s) that the subject matter of the required search is sufficiently small and closely related as to be capable of examination together. Specifically, Applicants request examination of Groups IV-VI together since SEQ ID NOs: 14, 16, and 18 as recited in Groups IV, V, and VI, respectively share structure and functional characteristics such that a search of each Group would not be an undue burden on the Office. Applicants provide the Examiner with a BLAST search result provided in Tab A which shows that SEQ ID NOs: 14 and 18 share 92% overall sequence identity; SEQ ID NOs: 14 and 16 share 96% overall sequence identity; and SEQ ID NOs: 16 and 18 share 96% overall sequence identity. Furthermore, Applicants argue that SEQ ID NOs: 14, 16, and 18 share 100% sequence identity at the nucleotide level at specific domains within the protein. Because of these reasons, Applicants argue that there is significant

shared structural similarity between SEQ ID NOs: 14, 16, and 18 and a search of each Group reciting these sequences would not be unduly burdensome on the Examiner.

Applicant's traversal and arguments have been fully considered, but are not found persuasive. It should be noted that the Examiner has fully considered the BLAST search results provided by Applicants. Further, the Examiner acknowledges that SEQ ID NOs: 14 and 18 share 92% overall sequence identity; SEQ ID NOs: 14 and 16 share 96% overall sequence identity; and SEQ ID NOs: 16 and 18 share 96% overall sequence identity. However, this degree of sequence identity shared amongst SEQ ID NOs: 14, 16, and 18 does not lessen the burden of search on the Examiner because as noted by Applicants in their traversal filed October 13, 2006, at page 1, third paragraph, "[T]he claims are directed to nucleic acid molecules comprising a nucleotide sequence having at least 85% sequence identity to SEQ ID NOs: 14, 16, or 18, respectively, vectors, cells comprising said nucleic acid molecules, and a method of making a polypeptide following expression of said isolated nucleic acid molecules." Given the claims, the full context in which the sequences appears must be examined, that is, each potential reference must be read and analyzed to determine if it contains one of the 3 sequences recited in Groups IV-VI. When this is considered in light of the fact that the claims read on nucleotide sequences having at least 85% sequence identity to one of the 3 sequences recited in Groups IV-VI, such a search may return many thousands of polynucleotide hits, each of which must be further considered as to vectors and cells comprising one of the 3 sequences recited in Groups IV-VI, and a method of making a polypeptide following the expression of one of the 3 sequences recited in Groups IV-VI.

In light of these many variables, this is considered to constitute a very serious burden.

Further, the Examiner acknowledges that SEQ ID NOs: 14, 16, and 18 share 100% sequence identity at the nucleotide level at domains within the protein, however, since these specific domains are not what is necessarily being claimed, restriction for examination purposes is indicated as proper.

Applicants also request that the Examiner consider the application under MPEP 803.04, which states, "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction".

This request has been fully considered, but is not found persuasive because although the MPEP states that up to 10 sequences are considered reasonable, such guidelines were issued in 1996, and the size of the nucleotide sequence databases has doubled approximately every six months since then. Thus, the number of returned hits for nucleotide sequence searches has expanded dramatically since the time these guidelines were issued. Furthermore, and as discussed *supra*, in addition to the voluminous size of such databases, the context in which the sequences appears must also be examined, that is, each potential reference must be read and analyzed to determine if it contains one of the 3 sequences recited in Groups IV-VI. When this is considered in light of the fact that the claims read on nucleotide sequences having at least 85% sequence identity to one of the 3 sequences recited in Groups IV-VI, such a search may return many thousands of polynucleotide hits, each of which must be further considered as to vectors, cells comprising one of the 3 sequences recited in Groups IV-VI, and a method of making a polypeptide following the expression of one of the 3

sequences recited in Groups IV-VI. In light of these many variables, this is considered to constitute a serious burden.

Applicants also argue that the EPO conducted a search on each separate sequence, which returned identical search results. Applicant point the Examiner to Tab B provided by Applicant. Applicants also argue that requiring Applicant to file additional patent applications to individually prosecute the 3 inventions recited in Groups IV-VI would put an unreasonable financial burden on the Application.

These arguments have been fully considered but are not found persuasive because first, the Examiner has fully considered the EPO search provided by Applicants in Tab B. However, it should be noted that the EPO follows a unity of invention practice under § 1.475 while U.S. applications follow restriction practice under 35 U.S.C. 121. In this regard, the two are very different practices and what is practiced in one cannot be said to be relevant to what is practiced in the other. Second, the Examiner acknowledges that a financial burden may weigh on Applicants to file additional patent applications to individually prosecute the 3 inventions recited in Groups IV-VI. However, search and examination of each of Groups IV, V, and VI in one application would be abusively burdensome on the Patent Office for the reasons discussed in the previous restriction requirement mailed August 11, 2006, and for the reasons discussed above. In this regard, restriction for examination purposes is indicated as proper.

Claims 1-4 and 19-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Additionally, SEQ ID NOs: 14 and 16 are withdrawn from

further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction requirement in the reply filed on October 13, 2006.

Applicant is reminded that the Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Accordingly, claims 5-18 and SEQ ID NO:18 have been examined on the merits.

The requirement is still deemed proper and is therefore made FINAL.

Nucleotide Sequence Disclosures

It is noted that the instant application meets the requirements of 37 C.F.R. §1.821-1.825.

Specification

Applicant's reference to priority in the first sentence of the specification is acknowledged.

Drawings

The drawings filed on March 20, 2004 are acknowledged and have been accepted by the Examiner.

Information Disclosure Statement

Applicant's information disclosure statement filed July 22, 2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR §1.97. Accordingly, the Examiner has considered the information disclosure statement, and a signed copy is enclosed herewith.

Applicant's information disclosure statement filed November 22, 2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR §1.97. Accordingly, the Examiner has considered the information disclosure statement, and a signed copy is enclosed herewith.

Applicant's information disclosure statement filed July 21, 2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR §1.97. Accordingly, the Examiner has considered the information disclosure statement, and a signed copy is enclosed herewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-18 are rejection under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,859,204, submitted and made of record as Citation #5 on Applicant's information disclosure statement filed July 22, 2004. It is noted that U.S. Patent No. 5,859,204 herein will be referred to as '204.

Claim 5 is drawn to an isolated nucleic acid molecule comprising a nucleotide sequence having at least 85% sequence identity to SEQ ID NO:18, wherein said nucleotide sequence encodes a polypeptide characterized by high-level expression. Claims 6-14 are dependent on claim 5 and include all the limitations of claim 5 with the further limitations wherein the isolated nucleic acid molecule comprises a sequence encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:19; a DNA construct or vector comprising said nucleic acid molecule; and a cell comprising said vector. Claims 15-18 are drawn to a method of producing a polypeptide comprising introducing into a cell an isolated nucleic acid molecule comprising a nucleotide sequence having at least 85% sequence identity to SEQ ID NO:18, wherein said nucleotide sequence encodes a polypeptide characterized by high-level expression, culturing said cell under conditions to allow expression of said nucleotide sequence and further isolating said polypeptide.

'204 discloses SEQ ID NO:38, which is an isolated nucleic acid molecule comprising a nucleotide sequence having at least 85% sequence identity to SEQ ID NO:18 of Applicant's invention (see attached sequence alignment). It is noted that SEQ ID NO:38 disclosed by '204 encodes a polypeptide characterized by high-level expression (see column 4, lines 40-67). It is also noted that SEQ ID NO:38 disclosed

by '204 encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:19 of Applicant's invention. '204 also discloses a DNA construct or vector comprising SEQ ID NO:38 and a cell comprising SEQ ID NO:38 (see column 12, lines 59-67 through column 13, lines 1-49 for example). '204 also discloses methods of producing SEQ ID NO:38 comprising culturing a cell expressing SEQ ID NO:38 and further isolating the protein (see column 12, lines 59-67 through column 13, lines 1-49, for example).

Therefore, '204 anticipates claims 5-18.

Claims 5-18 are rejection under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,458,563, submitted and made of record as Citation #9 on Applicant's information disclosure statement filed July 22, 2004. It is noted that U.S. Patent No. 6,458,563 herein will be referred to as '563.

'563 discloses and claims SEQ ID NO:37, which is an isolated nucleic acid molecule comprising a nucleotide sequence having at least 85% sequence identity to SEQ ID NO:18 of Applicant's invention (see attached sequence alignment and claim 1). It is noted that SEQ ID NO:37 disclosed by '563 encodes a polypeptide characterized by high-level expression (see Background of the Invention, for example). It is also noted that SEQ ID NO:37 disclosed by '563 encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:19 of Applicant's invention. '563 also discloses and claims a vector comprising SEQ ID NO:37 and a cell comprising SEQ ID NO:37 (see claims 2-7, for example). '563 also discloses and claims a method of producing SEQ ID NO:37 comprising culturing a cell expressing SEQ ID NO:37 (see claim 8, for example).

Therefore, '563 anticipates claims 5-18.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg
March 20, 2008

/Terra Cotta Gibbs/